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Review

Overview of tight fit and infection prevention benefits of respirators (filtering face pieces)

J.K. Knobloch a,*, G. Franke , M.J. Knobloch , B. Knobling , G. Kampf

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SUMMARY

Regulations for measures to protect against SARS-CoV-2 transmission vary widely around the world, with very strict regulations in Germany where respirators (filtering face piece FFP2 or comparable) are often mandatory. The efficiency of respirators, however, depends essentially on the tight facial fit avoiding the bypass of contaminated air via gaps between mask and wearer's face. The facial fit can be verified in a fit test. The aim of this review was to describe the quantitative fit test results depending on the respirator designs. A literature search revealed 29 suitable studies. Of all respirators with circumferential head straps, three-panel folded dome-shaped respirators showed the best fit (80.8% of 4625 fit tests passed), followed by rigid-dome-shaped respirators (72.4% of 8234 fit tests passed), duckbill-shaped respirators (31.6% of 2120 fit tests passed), and coffee-filter-shaped respirators (30.9% of 3392 fit tests passed). Respirators with ear loops showed very poor tight fit (3.6% of 222 fit tests passed). In four randomized control trials, single-use respirators were not shown to be superior to surgical masks for the prevention of laboratoryconfirmed viral respiratory infections, even when adjusted with a fit test. Therefore, we consider the mandatory use of respirators to be disproportionate and not supported by evidence. Further evidence should be generated, in which scenarios respirators might provide an effective benefit as part of occupational health and safety. For situations with confirmed benefits, only high-quality disposable respirators with head straps or respiratory protective equipment of higher protective levels should be used.

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Introduction

Particle-filtering face pieces (FFP) are disposable half-mask orinasal respirators (non-reusable, NR) which are generally used as part of personal protective equipment (PPE) as an occupational safety measure [1,2]. The use of PPE in terms of occupational safety requires trained handling of the individual components of the PPE. In the context of the COVID-19 pandemic, the use of respirators was also recommended for

E-mail address: j.knobloch@uke.de (J.K. Knobloch).

^a Institute of Medical Microbiology, Virology, and Hygiene, Department for Infection Prevention and Control, University Medical Center Hamburg-Eppendorf, Hamburg, Germany

^b University Medicine Göttingen, Göttingen, Germany

^c University Medicine Greifswald, Greifswald, Germany

^{*} Corresponding author. Address: University Medical Center Hamburg-Eppendorf, Institute for Microbiology, Virology and Hygiene, Department for Infection Prevention and Control, Martinistraße 52, 20251 Hamburg, Germany. Tel.: +49 40 7410 51720.

persons not specifically trained in their use in several countries and was even made mandatory in some areas.

Whereas in many countries around the world mandatory protective measures imposed by the government have been withdrawn, in Germany, curiously the regulations have been tightened even further with a partial respirator obligation [3]. For a transmission-reducing effect a continuously assured tight fit of respirators, achieving a seal of the mask to the face such that air cannot bypass filtration via gaps between mask and wearer's face, has been deemed necessary [4]. That is why a systematic literature search on this topic was recommended [5].

The tight fit of respirators can be determined using two different methods [6]. In qualitative fit testing, different aerosolized flavours can be used and the subjects report whether they can perceive the taste of the test substance nebulized inside a tight hood. The test is considered as failed if the flavour is perceived while wearing the respirator [6]. If the flavour is not perceived with the respirator in place, but is consciously perceived without the respirator, the test is considered to be passed. Quantitative fit testing involves measuring the number of measurable particles outside and inside the respirator while being worn. The calculated quotient is the fit factor [6]. For respirators classified as FFP2 (European standard), N95 (US standard), KN95 (Chinese standard) and KF94 (South Korean standard), a modified fit test is used compared to respiratory protective equipment with higher protection levels (e.g. with FFP3 respirators). For FFP2 and similar respirators only a defined particle size is determined in quantitative fit tests, which are typically almost completely retained by the typically used filter material. When performing a quantitative fit test, the fit factors are continuously measured during standardized movements and activities (normal breathing, deep breathing, turning the head, raising and lowering the head, speaking, bending the upper body forward, and final normal breathing) and subsequently an overall fit factor is determined. According to common occupational health and safety standards, a correct fit of respirators is assumed if a fit factor of \geq 100 is achieved [1,6].

For disposable respirators (NR), the market offers a large number of different shape types (exemplary selection in Figure 1). Respirators can be differentiated according to their shape and the way in which the respirator is attached to the head of the person wearing it. In terms of shape, dome-shaped respirators, which are rigidly preformed (Figure 1A) or threepanel folded (Figure 1B, C, H), are distinguished from respirators consisting of only two folded planes, in which the fold seam runs horizontally (duckbill shape, Figure 1D, E) or vertically (coffee filter shape, Figure 1F, G, I, J). In most industrialized countries, respirators with head straps (Figure 1A-G) were widely used in healthcare before the onset of the pandemic. In the case of fixation with head straps, a distinction is made between the principle of one head strap that is movably deflected at the edges of the respirator (Figure 1A, D, E, F) and two separately attached upper and lower head straps of different lengths (Figure 1B, C, G). With the onset of the pandemic, respirators with ear loops (Figure 1H-J) were increasingly used in healthcare as well. In the case of respirators with ear loops, the ear loops can be connected behind the head by using technical aids (Figure 1H, I) and thus the respirator body can be fixed to the head of the person wearing it with higher contact pressure. In the case of some respirators,



Figure 1. Exemplary shape types of disposable respirators. Domeshaped respirators, which are rigidly preformed (A) or three-panel folded (B, C, H), as well as respirators consisting of two folded planes in which the fold seam runs horizontally (duckbill shape, D, E) or vertically (coffee filter shape, F, G, I, J) are displayed. The respirators can be fixed to the head of the person wearing them with head straps (A–G) or ear loops (H–J). In the case of head straps, one single head strap can be movably deflected at the edges of the mask (A, D, E, F) or head straps of different lengths are attached (B, C, G). For respirators with ear loops, technical aids can be used to connect the ear loops behind the head (H, I). Another important distinguishing criterion is the presence of an exhalation valve (B, D, F).

the manufacturer already supplied these technical aids during distribution, so that it must be assumed that the suitability testing was carried out with the technical aid. Some respirators have an exhalation valve (Figure 1B, D, F), which considerably reduces the airway resistance during exhalation at physically strenuous activities. For respirators with an exhalation valve, it must be noted that patient protection is limited in the case of infectious personnel, so that these types of respirators were not recommended during the SARS-CoV-2 pandemic.

The aim of our review was therefore to evaluate the results of quantitative fit tests stratified according to different respirator types. Furthermore, we analysed randomized control trials on the efficacy of medical masks and respirators on the prevention of viral respiratory tract infections.

Methods

A PubMed literature search was performed on September 14th, 2022 using the terms 'quantitative fit test' in combination with 'respirator', 'FFP2', 'N95', 'KN95', 'KF94' or 'mask'. Due to the different methods of fit-testing respirators classified as FFP3 and the resulting poor comparability, the term 'FFP3' was not used in the literature search. All publications identified with the search strategy, as well as additional sources identified as appropriate during the literature review, were reviewed for clearly evaluable information on the results of a quantitative fit test for individual respirator types. Only data on disposable (NR) respirators that met the following minimum criteria were included for further analysis:

- standardized quantitative fit test with pass limit of a fit factor of >100;
- clear assignment of the results of the fit test to individual respirator types (information on manufacturer and type designation or illustration of the respirator in the publication);
- at least two different subjects per respirator type;
- clear indication of the number of subjects with successful and failed fit tests:
- test results without modifications of the respirator or facial morphology;
- test results with first use of the respirator;
- testing in a medical context.

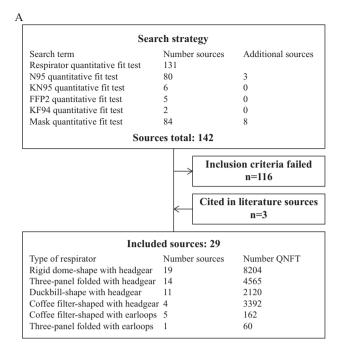
From studies with testing of respirators under different conditions (e.g. repeated use, disinfection of the respirators, testing with modified movement patterns, etc.) only those respective data sets were included that fulfilled the abovementioned conditions. For all studies, only the overall results (pass/fail or overall fit factor) were included in the analysis. Partial results of individual steps of the quantitative fit tests were not included. In addition, mean or median values of the measured fit factors were evaluated where available. In the following text, quantitative fit tests are referred to only as fit tests for better readability.

Randomized controlled trials (RCTs) were reviewed for comparative evaluation of the efficacy of respirators and surgical masks for the prevention of viral respiratory infections. A search was conducted on PubMed on October 17th, 2022 using the terms 'N95 randomized controlled' as well as 'FFP randomized controlled'. Studies were included if they were RCTs that directly compared rates of viral respiratory infections between wearers of surgical masks and respirators in healthcare settings and if participants in the group with respirators had performed at least one qualitative fit test before the start of the study and had thus demonstrably successfully passed a fit test. Studies were excluded if the effect was examined in the home setting or if only respirators were examined.

Results

Fit tests with respirators

The search strategy for quantitative fit tests identified a total of 29 studies (Figure 2A), which presented information on



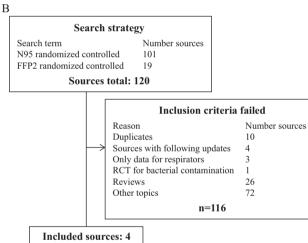


Figure 2. Flow charts illustrating the search strategies for the review. The search strategies for evaluating quantitative fit tests (A) and for randomized control trials comparing medical masks and FFP masks (B) are displayed.

Table IResults of fit tests depending on the shape type of respirators

Type of respirator	Type of fixation	No. of studies	No. of QNFTs	Overall QNFT pass rate ^a	Mean ^a (no. of QNFT/studies)	Median ^a (no. of QNFT/studies)
Three-panel folded respirator (dome shape)	Head straps	15	4625	80.8%	141.5-220.9 (2097/6)	139-200 (28/3)
Rigid respirator (dome shape)	Head straps	20	8234	72.4%	4.8-187.8 (402/10)	5.6-200 (58/5)
Respirator with duckbill shape	Head straps	11	2120	31.6%	29-152.7 (80/4)	21-145 (202/3)
Respirator with coffee filter shape	Head straps	4	3392	30.9%	13.5-110.7 (407/1)	_
Three-panel folded respirator (dome shape)	Ear loops	1	60	8.3%	43 (60/1)	43 (60/1)
Respirator with coffee filter shape	Ear loops	5	162	1.9%	2.2-11.4 (132/4)	3-39 (90/1)

QNFT, quantitative fit test.

^a Mean/median refers to the indicated values of the fit factors of the individual studies if indicated; the values might not be representative for all studies (details see Supplementary Tables).

Table II Results of randomized clinical trials

Source	Departments (no. of	Usage	Surgical mask				N95 respirator					P-value
	hospitals)	-	Type/ manufacturer	Endpoint ^a	Cases	No.	Type/ manufacturer	Fit test passed	Endpoint ^a	Cases	No.	_
Loeb <i>et al</i> . [11] Emergency departments, medical and paediatric wards (8)	Emergency departments,	Targeted use of surgical	Unknown	LCI ^b	50	212	Unknown	100%	LCIb	48	210	0.86
	medical and paediatric	mask or respirator during		LCV ^c	20	212			LCV ^c	22	210	0.72
	activities with persons		ILI	9	212			ILI	2	210	0.06	
	with febrile respiratory infections		CRI ^d	13	212			CRI ^d	13	210	0.98	
[9] pulmonology wards (15) respi with throu	Emergency departments,	Surgical masks or	Type 1820/3M	LCI	5	492	Type 9132/3M	98.9%	LCI	3	461	0.54
	pulmonology wards (15)	respirator (with and		LCVI	13	492			LCVI	8	461	0.50
	without fit test) worn		ILI	3	492			ILI	1	461	0.37	
	throughout shift (average		CRI	33	492			CRI	21	461	0.60	
	wear time 4.9-5.2 h)	Type 1820/3M	LCI	5	492	Type 9132/3M	Not	LCI	0	488	_	
			LCVI	13	492		perfomed	LCVI	5	488	0.11	
			ILI	3	492			ILI	2	488	0.66	
			CRI	33	492			CRI	16	488	< 0.05	
MacIntyre et al. Emergency departments, Surgical masks or respirator worn throughout shift. Surgical masks worn throughout shift; targeted use for respirators	respirator worn	Type 1817/3M	LCI	1	572	Type 1860/3M	97.4%	LCI	3	581	0.32	
			LCVI	19	572			LCVI	13	581	0.44	
			ILI	4	572			ILI	6	581	0.54	
	Surgical masks worn		CRI	98	572			CRI	42	581	< 0.05	
	throughout shift;	Type 1817/3M	LCI	1	572	Type 1860/3M	97.4%	LCI	2	516	0.59	
	targeted use for		LCVI	19	572			LCVI	17	516	0.99	
	respirators		ILI	4	572			ILI	2	516	0.49	
			CRI	98	572			CRI	61	516	0.28	
Radonovich	Outpatient departments,	Surgical mask or	Type 15320/	LCI	193	2668	Types 1860.1860S,	Not	LCI	207	2512	0.18
et al. [10] emergency rooms (7	emergency rooms (7)	gency rooms (7) respirator throughout shift with self- assessment of adherence to the measure	Precept, as	LCVI	417	2668	and 1870/3M,	described	LCVI	371	2512	0.39
			well as type	ILI	166	2668	as well as types		ILI	128	2512	0.08
			47107/ Kimberley Clark	CRI	1711	2668	PFR95-270 and PFR95-274/ Kimberley Clark		CRI	1556	2512	0.10

a LCI, laboratory-confirmed influenza; LCVI, laboratory-confirmed virus; ILI, influenza-like illness; CRI, clinical respiratory illness.
 b In this study, defined as detection by polymerase chain reaction or a ≥4-fold increase in serum antibodies to circulating influenza strain antigens.
 c In this study, defined as the detection of other viral respiratory pathogens by polymerase chain reaction.
 d In this study, defined as a visit to a physician for a respiratory infection.

the pass and fail rates of the respective group of tested respirators for clearly assignable types (Table I and Supplementary Tables \$1-\$5). In 15 studies, it was also possible to obtain clear information on the mean and/or median of the values determined for the fit factors, but their evaluated values cannot be representative for all studies conducted (for details see Supplementary Tables S1-S5). In 15 studies, data were collected on three-panel folded respirators with head straps for a total of 4625 fit tests (Table I and Supplementary Table S1). For this respirator type, 80.8% of initial fit tests were passed. The mean values of the fit factors for this respirator type ranged from 141.5 to 220.9 (six studies, 2097 fit tests). The median could only be determined for three studies and ranged from 139 to 200 (28 fit tests). Rigid respirators (dome shape) with head straps showed a pass rate of 72.4% (20 studies, 8234 fit tests). The mean values of the fit factors ranged from 4.8 to 187.8 (10 studies, 402 fit tests) and the median ranged from 5.6 to 200 (five studies, 58 fit tests). Rigid respirators with low fit factors were most common among infrequently tested manufacturers (Table I and Supplementary Table S2). Duckbill-shaped respirators with head straps (Table I and Supplementary Table S3) had a 31.6% pass rate of fit tests (11 studies, 2120 fit tests). The mean values of the fit factors ranged from 29 to 152.7 (four studies, 80 fit tests) and the median ranged from 21 to 145 (three studies, 202 fit tests). Respirators with coffee filter shape and head straps (Table I and Supplementary Table S4) showed a pass rate of fit tests of 30.9% (four studies, 3392 fit tests). Only in one study with 407 fit tests were mean values of the fit factors of this respirator type available from different manufacturers, ranging from 13.5 to 110.7.

For respirators with ear loops, only five studies with a total of 222 fit tests were found on respirators with coffee filter shape (N = 60, Table I and Supplementary Table S5) and threepanel folded dome-shaped respirators (N = 162, Table I and Supplementary Table S6). Overall, only 3.6% of the fit tests were passed (8.3% for dome shaped respirators, 1.9% for coffee-filter-shaped respirators). The mean and median fit factors of three-panel folded respirators with ear loops were 43 (one study, 60 fit tests). The mean values of the fit factors ranged from 2.2 to 11.4 for respirators with coffee filter shape (four studies, 132 fit tests). The median ranged from 3 to 39 (one study, 90 fit tests). Interestingly, in this study, a threepanel folded respirator with the ability to adjust the length of the ear loops on the respirator performed better (median 39, vs 3 and 4 for non-adjustable ear loops) [7]. However, even for the respirator with adjustable loop length, the fit test was passed in only four out of 30 cases.

RCTs on the protective effect of respirators and surgical masks

With the search strategy conducted on randomized comparative studies of the effectiveness of medical masks and respirators for the prevention of viral respiratory infections in healthcare workers, in total four studies were identified (Figure 2B, Table II). For three studies, there was clear information on the types of respirators used [8–10]. In these studies, only respirators with head straps but different respirator body shapes were used. In the fourth paper, no information was supplied on the respirator type. However, it can be assumed that respirators of high quality were also used, since only

subjects who passed a fit test were included in the respirator group.

Two studies considered the incidence of laboratoryconfirmed influenza as the primary endpoint and the incidence of other respiratory infections as secondary endpoints [10,11]. Two papers evaluated multiple forms of respiratory infections as primary endpoints [8,9]. None of the studies showed superiority of tight-fitting respirators (by fit test) over surgical masks for the endpoints of laboratory-confirmed influenza, laboratory-confirmed viral respiratory infections, and influenza-like respiratory infections. Two studies showed, in part, a significantly lower number of cases in the continuously worn respirator groups versus the surgical mask groups for the clinical respiratory tract infection endpoint [8,9]. Interestingly, in a study with two respirator groups (with and without a fit test), this observation was made only for the wearers of respirators without a fit test but not for the wearers of respirators with a fit test [9]. In a post-hoc analysis to exclude confounding factors, when both groups of respirators (with and without fit test) were combined in this study, there was a comparable significant reduction in the endpoints of laboratory-confirmed viral respiratory tract infections and clinical respiratory tract infections for the comparison groups of all respirators and surgical mask for the type of facility ('hospital level') and type of face cover used [9].

Discussion

From the point of view of occupational health and safety requirements, the most important factor for the protection of a person by wearing a disposable respirator is the tight fit of the respirator, even during physical activity, which is associated with the protective effect [1,2]. In the technical development, approval, and quality control of disposable respirators, a standardized pliable elastomeric head form is regularly used (Sheffield dummy head), which represents male European facial dimensions [12,13]. This dummy does not represent the diversity of people working in the healthcare sector around the world including their variable head forms and is likely to have a non-negligible effect on fit test results of commercially available respirators. Few efforts were made to overcome these problems in the laboratory testing of respirators [13—15].

The tight fit of respirators during patient care or other movements of the head depends on many different factors such as the shape of the face [16,17], the presence of beards, stubble or any hair in the region where a face mask seals [18,19], the knowledge of the person using the respirator, and the shape of the respirator. An important aspect of the tight fit of a respirator is also the way in which the respirator is fixed to the head of the person wearing it. Before the pandemic, (almost) exclusively respirators with head straps were used in medical facilities, whereas since the initial shortage of respirators was eliminated at the beginning of the pandemic, the market has been dominated by respirators with ear loops (own observation). It should be noted here that in the scientific literature with studies conducted before the pandemic with respirators of the N95 and KN95 type with coffee filter shape, this shape type was also used, but with head straps that were often adjustable in length to the head size.

The data collected in the studies included in this review indicate a relative superiority of dome-shaped respirators

(three-panel folded or rigidly shaped; Figure 1A-C) with head straps compared with respirators consisting of two folded planes (duckbill shape, or coffee filter shape; Figure 1D-G) with the same type of attachment. The superiority of threepanel folded respirators compared to other shape types could also be traced in a number of other studies, which could not be included in this review due to lack of partial data [20-23]. A clear inferiority was shown for respirators with ear loops compared to respirators with head straps as the attachment type. In another study, which was not included because of the criteria selected, all respirators tested with ear loops failed an upstream qualitative fit test, in contrast to respirators with head straps, so no quantitative fit test was included in the study [24]. Indirectly, however, this study demonstrated an inadequate tight fit for an additional 12 respirators of the coffee filter shape with ear loops from different manufacturers. The disadvantage of fastening respirators by ear loops was confirmed experimentally by converting some respirators from fastening by means of head straps to lengthadjustable ear loops with the respirator body remaining unchanged, and subsequently an adequate tight fit could no longer be achieved despite the ear loops being adjustable to the anatomy [25]. For this reason, some governmental occupational safety organizations indicate that respirators with ear loops do not provide adequate protection as tight-fitting respiratory protective equipment [26].

The regulations imposed by the governments in individual countries for the prevention of public health problems during the pandemic now vary widely. They range from the abolition of mandatory requirements to the mandatory wearing of respirators in individual areas of society. In Germany, the assessment that a temporary respirator mandate represents an effective and rapid instrument for infection control was justified [4], among other things, by a review paper which, on the basis of the evaluation of six studies, stated that a mandate for face covering masks leads to a median reduction in incidence of 53% [27]. Interestingly, this review, citing a review published in 2016, claims that respirators (N95 or similar respirator) achieved greater effectiveness compared with a surgical masks, whereas the paper cited as supporting evidence clearly highlights that there was no significant difference in the prevention of respiratory tract infections with use of respirators or surgical masks by healthcare professionals [28]. The lack of superiority of respirators over surgical masks in the prevention of viral respiratory infections in healthcare workers was demonstrated in four randomized trials identified in this paper, although they involved personnel specifically trained in the use of respirators (with fit test performed) [8-11]. This observation was confirmed by a recent study, which also failed to observe superiority of respirators over masks for the acquisition of COVID-19 [29]. The conclusion drawn from some experts that respirators should be preferred from an infection prevention point of view for external and self-protection, especially in risk settings such as medical or nursing areas, is therefore not comprehensible, at least on the basis of data with persons wearing respirators [5]. This is particularly supported by a recent review which concluded that there is no advantage of respirators over surgical masks for preventing transmission of SARS, but that there may be side effects from the greater stress [30].

Due to the search and inclusion criteria, the review study addresses only the tight fit in terms of self-protection of respirator wearers, as quantitative fit tests only examine this issue. However, the literature review also provided evidence that respirators may be inferior even to surgical masks in terms of extraneous protection (reducing the release of secretions and aerosols from the upper airway). A recent study showed that surgical masks as well as respirators significantly reduced emissions during breathing, speaking, coughing, and chewing. However, surgical masks showed a 90% reduction in outward emissions compared with wearing no mask, whereas respirators showed a mean reduction of only 74% [31]. A test of restraint for external protection also showed the inferiority of a dualfold respirator with ear loops compared with a respirator with head straps but also a surgical mask [32]. As early as 2008, one study was able to show that, in contrast to significantly different protective effects during inhalation between respirators (with head straps) and surgical mask, no significant differences were observed in the external protective effect during exhalation [33]. One major paper that was used to justify the efficacy of general respirator use was a mathematicaltheoretical model that calculated the best protection when using very tightly fitted respirators on the index person and a contact person [34]. However, this work equated inhalation and exhalation leakage for the mathematical model. At most, this assumption can be adopted for an extremely tight-fitting respirator because exhalation creates positive pressure in the respirator body, whereas inhalation creates negative pressure. For respirators with ear loops, it can be assumed with a very high probability that the majority of exhaled air exits unfiltered at the edges of the respirator. This assumption was also supported by visualization in one study [35].

The respirators investigated in the included studies were exclusively single use (NR), which are not approved for repeated use. For persons trained in the use of respirators, a self-test at the beginning of use can help to improve the fit of the respirator [23]. However, even with successful fit testing, an optimal fit is not guaranteed for all types of activities. For example, several studies have shown that airtight fit is not continuously maintained during typical patient care activities [36,37]. These observations may be part of the explanation for why no difference in the prevention of viral respiratory infections was observed between respirators and surgical masks in RCTs, even among well-trained healthcare workers. The fact that in a post-hoc analysis in one study, the hospital level showed a comparable significant reduction in the endpoints of laboratory-confirmed viral respiratory tract infections and clinical respiratory tract infections points to the importance of training individuals in the use of respirators. An RCT on the effectiveness of respirators compared to surgical masks in households did not show a greater effectiveness of respirators over surgical masks or any reduction at all compared with households without mask use [38]. However, household members with use of surgical masks or respirators reported adherence to wearing the face covering of less than 50% in both groups already at the beginning of events, which decreased during the course and decreased more for respirators during the course compared with wearing a surgical mask. It is therefore reasonable to assume that, particularly for those not adequately trained in their use, leakage increases with prolonged wear due to body and facial movement, and overall compliance to correct respirator use in the home environment is low. Repeated use of respirators for occupational health and safety is not recommended based on the observation that even with very high-quality respirators with an optimal fit, simulated

multiple use decreases the protective effect [39,40]. Reuse of a respirator after removal should therefore only occur in exceptional cases and only by personnel specially trained in the donning and doffing process of respirators. This should only be applied to high-quality, well-fitting respirators with head straps. According to existing studies, the multiple use of a respirator with ear loops should be strictly rejected for all users because of an assumed further reduction of an already low protective effect.

The review has certain limitations. The chosen search strategy does not fully ensure that all publications on the topic of fit testing using quantitative fit tests were identified. Since in the USA and Canada, fit tests are mandatory for respirator wearers. the included studies are dominated by respirator types that are most common in North America. Therefore, the statements on the superiority of three-panel folded respirators cannot be generalized, since a few individual manufacturers dominate for almost all respirator types and comparable respirator types from other manufacturers can perform significantly differently in fit tests for the same shape. This is also indicated by the sometimes significantly worse pass rates and fit factors of individual rarer respirator brands in other respirator types. Therefore, further comparative studies on the fit of comparable respirator types from different manufacturers should be conducted. Since only particle sizes that are optimally suited for the detection of leakage at the respirator-skin contact surface are recorded during the fit testing of disposable respirator, no direct conclusion can be drawn regarding the risk of infection by viral pathogens. Respirators classified as FFP3 are recommended in some countries such as the UK. But they were not addressed in this review because the method for their facial fit testing is different. In the randomized studies included in the review, only a qualitative fit test was performed in three papers and no information on the type of fit test is available for one paper. Therefore, it cannot be excluded that these studies would produce different results if quantitative fit tests were performed.

Conclusion

Mandates to use respirators for untrained individuals outside of medical facilities as well as the continuous use in hospitals lack evidence and should be withdrawn. Respirators should only be used for specific occupational indications and after instruction in their effective use. Based on current evidence the mandatory use of respirators in selected settings to prevent viral transmission cannot be justified. Further studies should be performed to generate evidence concerning those scenarios in which the use of respirators provides an effective benefit for medical personnel as part of occupational health and safety. In situations with confirmed benefits, only high-quality respirators with head straps or respiratory protective equipment of higher protective levels should be used for well-trained personnel.

Conflict of interest statement

The authors declare that there is no conflict of interest. The views expressed herein are those of the authors and do not necessarily reflect those of the universities with which they are affiliated.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.jhin.2023.01.009.

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